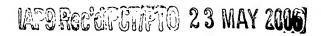
IAP12 Rec'd PCT/PTO 23 MAY 2006

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
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TRANSMITTAL LETTER TO THE UNITED STATES ATTORNEY'S DOCKET NUMBER BO31-013-US							
DESIGNATED/ELECTED OFFICE (DO/EO/US) ILS APROJUÊNTION MO Alf leavure sue MS.CFR 1.5)							
INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED							
	US2004/039680	November 23, 2004	November 23, 2003				
Treat		in a mammal with f	Idministration of				
	NT(S) FOR DO/EO/US Kawa, etal.						
		ates Designated/Elected Office (DO/EC	O/US) the following items and other information:				
1. 🔯	This is a FIRST submission of items ∞	oncerning a submission under 35 U.S.C. 371					
2.	This is a SECOND or SUBSEQUENT s	submission of items concerning a submission	n under 35 U.S.C. 371.				
3. 🔀	This is an express request to begin nat (5), (6), (9) and (21) indicated below.	ional examination procedures (35 U.S.C. 37	1(f)). The submission must include items				
4. 🔯	The US has been elected (Article 31).						
5. 🔀	A copy of the International Applicatio	n as filed (35 U.S.C. 371(c)(2))					
	a. X is attached hereto (required	d only if not communicated by the Internation	nal Bureau).				
	b. As been communicated by	the International Bureau.					
	c. is not required, as the appli	cation was filed in the United States Receivi	ing Office (RO/US).				
6.	An English language translation of th	e International Application as filed (35 U.S.C	C. 371(c)(2)).				
	a. is attached hereto.						
l	b. has been previously submitted under 35 U.S.C. 154(d)(4).						
7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))							
a. are attached hereto (required only if not communicated by the International Bureau).							
	b. have been communicated	by the International Bureau.					
c. have not been made; however, the time limit for making such amendments has NOT expired.							
d. An have not been made and will not be made.							
8.	8. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).						
9.	9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).						
10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).							
Items	11 to 20 below concern document(s	s) or information included:					
11.	An Information Disclosure Statement	under 37 CFR 1.97 and 1.98.					
12.	An assignment document for recording	ng. A separate cover sheet in compliance wi	th 37 CFR 3.28 and 3.31 is included.				
13.	A preliminary amendment.						
14.	An Application Data Sheet under 37 CFR 1.76.						
15.	A substitute specification.						
16.	A power of attorney and/or change of address letter.						
17. 🔲	A computer-readable form of the seq	uence listing in accordance with PCT Rule	13ter.2 and 37 CFR 1.821- 1.825.				
18. 🔲	A second copy of the published Inter	national Application under 35 U.S.C. 154(d)	(4).				
19.	A second copy of the English langua	ge translation of the international application	n under 35 U.S.C. 154(d)(4).				

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office. U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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20. Other items or information: The following fees have been submitted 21. Basic national fee (37 CFR 1.492(a))	20. Other items or information: The following fees have been submitted 21. Basic national fee (37 CFR 1.492(a))	U.S. APPLICATION NO. (if known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO. ATTORNEY'S DOCKET NUMBER 8031 - 013 - U.S.								
The following fees have been submitted 21. Basic national fee (37 CFR 1.492(a))	The following fees have been submitted 21. Basic national fee (37 CFR 1.492(a))									
21. Sasic national fee (37 CFR 1.492(a))	21. Stamination fee (37 CFR 1.492(a))	20. Other items or information:								
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21. Sasic national fee (37 CFR 1.492(a))	21. Stamination fee (37 CFR 1.492(a))	The foll	owing fees have h	een submitted				С	ALCULATIONS	PTO USE ONLY
22. Stamination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	22. Search fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims setisfy provisions of PCT Article 33(1)-(4)		•				\$300	_		
by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	22. 🔀 Exan	nination fee (37 CI	FR 1.492(c))						
All other situations	All other situations	If the written opin	nion prepared by IS	SA/US or the inte	rnational preliminary ex	xaminatio	n report prepared	\$	200	
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)									
IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				nal preliminary examina	ation repo	rt prepared by			
International Searching Authority	International Searching Authority	IPEAUS	indicates all claim	ns satisfy provision	ons of PCT Article 33(1))-(4)	\$0	\$	100	
previously communicated to the US by the IB	All other situations	Internation	onal Searching Au	thority			\$100		,00	
TOTAL OF 21, 22 and 23 = Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Total Sheets Extra Sheets Number of each additional 50 or fraction thereof. Number of each additional 50 or fraction thereof. RATE **Secondary of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). CLAIMS NUMBER FILED NUMBER EXTRA RATE **Total claims A 2 - 20 = 72	TOTAL OF 21, 22 and 23 = Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Total Sheets	previously	y communicated to	the US by the II	3		\$400			
sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Total Sheets Extra Sheets Number of each additional 50 or fraction thereof (round up to a whole number) LO - 100 = O /50 =	sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(ji)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Total Sheets Extra Sheets Number of each additional 50 or fraction thereof. RATE WO - 100 =								600	
The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Total Sheets Extra Sheets Number of each additional 50 or fraction thereof (round up to a whole number) RATE LOD - 100 = D /50 =	The fee is \$250 for each additional 50 sheets of paper or fraction thereof. Total Sheets		e listing in complia	ince with 37 CFF	ed in paper over 100 sh t 1.821(c) or (e) or com	eets (excl	luding gram listing in an			
thereof (round up to a whole number) LOD - 100	thereof (round up to a whole number) LOC - 100 = O /50 =	electronic medium) (37 CFR 1.492(j)).								
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). CLAIMS NUMBER FILED NUMBER EXTRA RATE \$ Total claims Q2 -20 = 72 x \$50 \$3600 Independent claims 2 -3 = 0 x \$200 \$ M MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$ 60 TOTAL OF ABOVE CALCULATIONS = \$ 4330	Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). CLAIMS NUMBER FILED NUMBER EXTRA RATE Total claims Q2 -20 = 72 x \$50 \$3600 Independent claims Z -3 = 0 x \$200 \$ MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$ MULTIPL	Total Sheets	Extra Sheets				RATE			
after the date of commencement of the national stage (37 CFR 1.492(h)). \$ \ \ \frac{36}{56}\$ CLAIMS NUMBER FILED NUMBER EXTRA RATE \$ Total claims Q 2 - 20 = 72	after the date of commencement of the national stage (37 CFR 1.492(h)). CLAIMS NUMBER FILED NUMBER EXTRA RATE \$ Total claims Q2 -20 = 72 x \$50 \$3600 Independent claims 2 -3 = 0 x \$200 \$ MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$60 TOTAL OF ABOVE CALCULATIONS = \$43300 Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½. Processing fee of \$130.00 for furnishing the English translation later to claimed priority date (37 CFR 1.492(i)). Fee for recording the enclosed assignment (37 CFR 1.21(h)). The ass	60 - 100 =	O /50 =				× \$250	\$	Ø	
Total claims Q 2 -20 = 72 x \$50 \$ 360 Independent claims 2 -3 = C x \$200 \$ 6 MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$ 6 TOTAL OF ABOVE CALCULATIONS = \$ 4330	Total claims Q2 -20 = 72	Surchame of \$130.00 for furnishing any of the search fee, examination fee, or the path or declaration								
Independent claims Z -3 = C x \$200 \$ MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$ 6 TOTAL OF ABOVE CALCULATIONS = \$ 4330	Independent claims Z -3 =	CLAIMS	NUMB	ER FILED	NUMBER EXTRA	4	RATE	\$		
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$ 60 TOTAL OF ABOVE CALCULATIONS = \$ 4330	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$ TOTAL OF ABOVE CALCULATIONS = \$ 4350 Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. Processing fee of \$130.00 for furnishing the English translation later tl claimed priority date (37 CFR 1.492(i)). Fee for recording the enclosed assignment (37 CFR 1.21(h)). The ass	Total claims	92	- 20 =			x \$50	\$		
TOTAL OF ABOVE CALCULATIONS = \$ 4330	TOTAL OF ABOVE CALCULATIONS = \$ 4330 Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. Processing fee of \$130.00 for furnishing the English translation later ti claimed priority date (37 CFR 1.492(i)). Fee for recording the enclosed assignment (37 CFR 1.21(h)). The ass			_ `	<u> </u>			_	Ø	-
1 4330	Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. Processing fee of \$130.00 for furnishing the English translation later ti claimed priority date (37 CFR 1.492(i)). Fee for recording the enclosed assignment (37 CFR 1.21(h)). The ass NO AVHORIZATION to Charge.									
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	Fee for recording the enclosed assignment (37 CFR 1.21(h)). The ass by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per proper The additional files.									
NA QUELO DA LA CIACA	by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per proper **Mary add/hondless: 40.00 per proper** **Add/hondless: 40.00 per p									
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The ass V or an appropriate cover sheet (37 CFR 3.28, 3.31) \$40.00 per proper	the additional fees.									
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a. 🔲	A check in the amount of \$	to cover the above fees is enclosed.		
ь. 🔀	Please charge my Deposit Account No. 502235 A duplicate copy of this sheet is enclosed.	in the amount of \$ 150.00 to cover the above fees.		
с. 🔲	The Commissioner is hereby authorized to charge any Account No A duplicate copy of this she	additional fees which may be required, or credit any overpayment to Deposit eet is enclosed.		
d. 🔲	Fees are to be charged to a credit card. WARNING: Into be included on this form. Provide credit card information	formation on this form may become public. Credit card information should not tion and authorization on PTO-2038.		
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.				
SEND A	ALL CORRESPONDENCE TO:	SIGNATURE Michael B. Fayber, Esq. NAME 32, 612 REGISTRATION NUMBER		

Certificate of Express Mailing

Under 37 CFR 1.10, I certify that the attached correspondence is being deposited with the United States Postal Service as Express Mail No. EV 669528748 envelope addressed to: Mail Stop: PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Date: May 23, 2006

Christina Dueñas

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Examiner: To Be Assigned
Yoshitaka Ichikawa, et al.)	Group Art Unit:
Serial No.: U.S. National Stage of)	
PCT/US2004/039680)	Docket No.: 8031-013-US
)	
Filed: Herewith)	Date Mailed: May 23, 2006
For: Treatment of a Condition in a)	
roi. Headilelli of a Condition in a)	
Mammal with Administration of)	
Compounds and Methods of Use)	

TRANSMITTAL LETTER

Honorable Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This submission is to effect entry of PCT Application PCT/US2004/039680 the United States National Stage under 35 U.S.C. § 371 and 37 C.F.R. § 1.495.

PATENT 8031-013-US

Accordingly, the following documents are transmitted:

1. Transmittal Letter for Submission under 35 USC 371 with Fee Sheet indicating a fee payment of \$150.00, reflecting the basic national stage fee of \$150.00

for a small entity under 37 C.F.R. § 1.492(a) (3 pages);

2. An Application Data Sheet Under 37 C.F.R. § 1.76 giving biographical

information on the inventors of the above-identified application as well as

details of the claim for priority based on a previously-filed provisional

application (2 pages); and

3. A copy of the above-identified PCT application. Because the above-identified

PCT application was filed in the United States Patent and Trademark Office,

the copy is not required under 37 C.F.R. § 1.495(b)(i). The copy is provided

for convenience (60 pages).

Priority under 35 U.S.C. §§ 119 and 365 is hereby claimed for the national stage

application. This priority is claimed to: (1) PCT Application No. PCT/US2004/039680,

filed on November 23, 2004, and designating the United States; and (2) United States

Provisional Patent Application Serial No. 60/524,698 filed on November 24, 2003, from

which PCT Application No. PCT/US2004/039680 claimed priority.

May 23, 2006

Respectfully submitted,

Michael B. Farber, Ph.D., Esq.

Reg. No.: 32,612

CATALYST LAW GROUP, APC 9710 Scranton Road, Suite 170

San Diego, California 92121

(858) 450-0099

(858) 450-9834 (Fax)

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